

201-15396



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06/24/2004 04:16 PM

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Subject: Environmental Defense comments on 4-Nananone, 2,6,8-Trimethyl (CAS# 123-18-2)

(Submitted via Internet 6/24/04 to oppt.ncic@epa.gov, hpv.chemrtk@epa.gov, boswell.karen@epa.gov, chem.rtk@epa.gov, lucierg@msn.com and Ehunt@adelphia.net)

Environmental Defense appreciates this opportunity to submit comments on the robust summary/test plan for 4-Nananone, 2,6,8-Trimethyl (CAS# 123-18-2).

The test plan and robust summaries for 4-nananone, 2,6,8-trimethyl, also named isobutyl heptyl ketone (IBHK), were submitted by Dow Chemical Company. The test plan and robust summaries are written in a clear and objective manner, and they contain a level of information consistent with the goals of the HPV program.

IBHK, according to the test plan, is produced exclusively by the Dow Chemical Company but is marketed for a number of uses, including the manufacture of an extraction solvent for mining and in the production of 2,6,8-trimethyl-4-nanol. IBHK can also be used in industrial cleaners and degreasers and its use in coating applications is being considered.

The sponsor considers that the potential for environmental exposures is limited because it is used as an industrial intermediate and solvent. Are data available on amounts of IBHK in waste streams or products, workplace monitoring and testing for residues in the general environment in proximity to where it is used?

There are no existing data for the three aquatic toxicology endpoints, nor for any of the mammalian health endpoints with the exception of acute toxicity data in rodents. These data gaps are appropriately addressed in the test plan by proposals to conduct fish, aquatic invertebrate, algae, genetic and combined repeat dose/reproductive/developmental toxicity studies. The sponsor also proposes to conduct a biodegradation study. We agree with the proposed new studies and make the following comments regarding them, as well as a couple of comments regarding existing data:

1. We recommend that the test substance for the toxicology studies represent the composition of the marketed material, which may contain as much as 4% nonanol, 2,6,8-trimethyl.
2. The combined repeat dose/reproductive/developmental toxicity study is a good choice, as it is unlikely that IBHK possesses strong toxic properties. Existing acute toxicity data indicate an LD50 of close to 10 g/kg.
3. Environmental fate and distribution estimates were obtained from models. These data are consistent with HPV requirements and we were pleased to see that fugacity modeling was conducted for environmental releases occurring in both water and air. As expected, the distribution was different for the two media.

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4 Has IBHK or the corresponding nonanol impurity been tested for hormonal activity by in vitro screening methods?

Thank you for this opportunity to comment.

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